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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,234	10/24/2003	Claus Lindvald Johansen	674509-2025.1	1385

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/693,234	Applicant(s) JOHANSEN ET AL.	
	Examiner Elizabeth Slobodyansky, PhD	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 and 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/722,938.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/04; 5/26/05; 6/28/05.</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a CIP of 09/722,938 now abandoned.

The amendment filed May 24, 2006 amending claims 10-12, 26 and 27 has been entered.

Claims 1-32 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-17 and 22-25, species LTAB and HOX, in the reply filed on May 24, 2006 (Remarks, pages 7-8) is acknowledged.

The traversal is on the ground(s) that "The Office Action provides no showing that search and examination of the claims would be an undue and serious burden. Indeed, Groups II-IV encompass only eight claims in total, Groups II and III accounting for three of those claims. Accordingly, the search and examination of Groups II and III along with the claims of Group I would only add three additional claims to the total number of claims to be searched, and there is no required showing in the Office Action that such an addition of three claims would result in an undue burden. Therefore, the restriction requirement is improper because it does not satisfy both requirements for restriction and should be withdrawn (Remarks, page 9, 2nd paragraph). This is not persuasive because the number of the claims is not necessarily the reasons for the restriction or rejoining. In the instant case the examination of all groups together requires additional search that is not required for the elected Group I and diverse

considerations. Applicants further argue regarding election of species that "The Office Action also alleges that the proteins IL-lra enzyme, Glucan lyase enzyme and HOX enzyme are unrelated and patentably distinct. Applicants respectfully disagree. Initially, the three proteins share fundamental similarities, such that the separation of the three into separate groups is unduly burdensome on Applicants. And, Applicants respectfully submit that the "restriction requirement" as applied to the proteins IL-lra enzyme, Glucan lyase enzyme and HOX enzyme is improper, and should have properly been drawn as a further election of species if an election between the enzymes was desired" (page 9, 1st paragraph). this is not persuasive because Applicants d not explain what are the fundamental similarities of the above enzymes. In fact, these enzymes are fundamentally different as having different structures, physico-chemical properties, functions and utilities.

The requirement is still deemed proper and is therefore made FINAL.

Claims 61-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 11, 2006.

With regard the requirement for the election of species of a quarternary ammonium compound is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a method for releasing any intracellular protein of interest (POI) using a membrane extracting composition causing "specific release" of POI. Therefore, the claims are drawn to a method of making of a genus of POIs. Said genus encompasses unlimited number of species having wildly different structures and functions. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. Structural features that could distinguish compounds in the genus from others in the protein classes are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance, is needed. The art teaches that the high level production and purity of a protein depend on the protein and its source whether said source is a naturally-occurring or recombinant cells. The art of protein purification in general is highly developed. However, the development of an appropriate purification scheme for a specific protein with known characteristics requires additional trial and error experimentation. Claim 1 further recites "conditions sufficient for the specific release of the POI". Such conditions encompasses a great number of

parameters and elements. The specification does not provide a correlation between the specific POI and said conditions. Claims 3-12 recite specific extracting compositions, specific temperatures and pH optimum. The specification does not describe the correlation between POI and said conditions. The specification discloses the production of *Chondrus crispus* HOX in the yeast *Hansenula polymorpha* using an engineered DNA of SEQ ID NO:22 that accommodates yeasts codon preferences. The extraction of thus expressed HOX was carried out using specific quaternary ammonium salt as an extracting agent under specific conditions that were empirically found.

Claims 22-25 recite POI that is HOX (hexose oxidase). The genus of HOXs encompasses any HOX from any source. The specification teaches a single representative species of HOXs, *Chondrus crispus* HOX. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being HOX. Claims 16-18 are included in this rejection because the recitation of variant, homologue, etc. negates the reference to SEQ ID NO:22. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

With regard to a process, the single representative is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed tremendously diverse genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the

time the instant application was filed.

Claims not specifically discussed above are rejected as dependent from the rejected base claim.

Claims 1-17 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the specific release HOX encoded by SEQ ID NO:2, does not reasonably provide enablement for a method for the specific release of any POI. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification discloses the production of *Chondrus crispus* HOX in the yeast *Hansenula polymorpha* using an engineered DNA of SEQ ID NO:22 that accommodates yeasts codon preferences. The extraction of thus expressed HOX was carried out using specific quarternary ammonium salt as an extracting agent under specific conditions that were empirically found.

The claims are drawn to "the specific release" of any protein under "sufficient conditions". There is not guidance in the specification as to how to find said sufficient conditions given that proteins differ widely in properties. On the other hand claims 3-12 recite specific extracting compositions, specific temperatures and pH optimum that are not necessarily "sufficient" for the specific release of any POI. The state of the art is such that purification of proteins requires trial and error experimentation.

Without sufficient guidance, beyond that provided, obtaining the specific release of any POI is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1(c) recites "causing the POI to be released from the cell under conditions sufficient for the specific release of the POI and in soluble form". The term "specific release is not commonly accepted in the art. the specification teaches that "The term "specific release" means that the specific activity of the POI is higher than when it has

been extracted by mechanical means - such as by use of a bead mill or a cell homogenizer operating with a french press principle" (page 12, last paragraph). Therefore, the term is defined relative to something that is variable and uncertain rendering the metes and bounds of the term unclear. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, the meaning of "specific release and in a soluble form" is unclear (emphasis added).

Regarding claim 13, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 22-25 recite "variant, homologue, derivative". These terms do not have an art accepted meaning. The difference among them is also unclear.

Claims not specifically rejected are included as dependent from the rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundhey et al.

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Sundhey et al. (Small Ruminant Research (May 1995) Vol. 16, No. 3, pages 251-261) teach the extraction of membrane proteins of different molecular weights from goat testicular cells using CTAB.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD

Primary Examiner

Art Unit 1652

June 25, 2006